AD_____

Award Number: DAMD17-99-1-9576

TITLE: Roundtable on Biomedical Engineering Materials and Applications

PRINCIPAL INVESTIGATOR: Richard Chait, Ph.D.
Teri Thorowgood
Dr. Toni Marechaux

CONTRACTING ORGANIZATION: National Academy of Sciences
Washington, DC 20418

REPORT DATE: September 2002

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

# REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188



| 1. AGENCY USE ONLY (Leave blank) | 2. REPORT DATE | 3. REPORT TYPE AND DATES COVERED |
|---|---|---|
| | September 2002 | Final (1 Sep 99 - 31 Aug 02) |

**4. TITLE AND SUBTITLE**

Roundtable on Biomedical Engineering Materials and Applications

**5. FUNDING NUMBERS**

DAMD17-99-1-9454

**6. AUTHOR(S)**

Richard Chait, Ph.D.
Teri Thorowgood
Dr. Toni Marechaux

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

National Academy of Sciences
Washington, DC 20418

**E-Mail:** tthorowg@nas.edu

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSORING / MONITORING AGENCY REPORT NUMBER**

**11. SUPPLEMENTARY NOTES**

**12a. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**12b. DISTRIBUTION CODE**

**13. ABSTRACT** *(Maximum 200 Words)*

The National Materials Advisory Board (NMAB) held a BEMA Roundtable workshop on 07-08 February 2002 (postponed from 04-05 October 2001 due to issues pertaining to 9/11terrorist attack) at the National Reseach Council (NRC), Washington DC. The invited speakers were Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; Ron Greene, Wilmer, Cutler & Pickering; Barbara Rather, Dow Corning; Nelson Lazear, Bayer; James Harper, PolicyCounsel.com; and George Brode, Integra LifeSciences. The speakers addressed the topic of pathways to innovation, including examining the current status and gauge the effects of biomaterials shortages, identifying key barriers to biomaterial availability, and discussing forging biomaterials supplier. The meeting provided opportunities to explore with key stakeholders and decision makers future options in assuring biomaterials availability.

NMAB held the fourth BEMA meeting on 22-23 July 2002 at the NRC's J. Erik Jonsson Woods Hole Center, Woods Hole, MA. The technical speakers were Nancy Parenteau, Amaranth Bio, Inc.; Joshua Jacobs, Rush University Medical College; Eric Amis, NIST; Doyle Gantt, FDA, Center for Devices and Radiological Health; Anthony Ratcliffe, Advanced Tissue Sciences; Jack Lemons, University of Alabama – Birmingham; Rodney White, UCLA; John Watson, National Institutes of Health; and Michael Jaffe, Medical Device Concept Laboratory. The meeting goals were to continue planning for a "Science-Based Testing" workshop, now scheduled for 11-12 February of 2003, and to discuss issues of interest including implant retrieval (and associated logistics, database issues, privacy, etc); differentiation of biologics, devices, and combination products; industry perspective of where advanced biomedical materials are headed and their related testing requirements (e.g., nano, MEMS, tissue engineering), and current testing protocols.

| 14. SUBJECT TERMS | 15. NUMBER OF PAGES |
|---|---|
| biomedical, materials, roundtable | 5 |
| | 16. PRICE CODE |

| 17. SECURITY CLASSIFICATION OF REPORT | 18. SECURITY CLASSIFICATION OF THIS PAGE | 19. SECURITY CLASSIFICATION OF ABSTRACT | 20. LIMITATION OF ABSTRACT |
|---|---|---|---|
| Unclassified | Unclassified | Unclassified | Unlimited |

## Table of Contents


Cover..... 1

SF 298..... 2

Table of Contents..... 3

Introduction..... 4

Body..... 4

Key Research Accomplishments..... 4

Reportable Outcomes..... 5

Conclusions..... 5

## Introduction

The Biomedical Engineering Materials and Applications (BEMA) Roundtable will provide a forum for identifying major opportunities for applying engineering principles to create and improve clinical performance of medically useful materials and devices, including implants, as well as for discussion of strategies for overcoming obstacles—technical, legal, or cultural—that impede transition of new materials and devices to clinical application.

## Body

### Roundtable Meetings

The National Materials Advisory Board (NMAB) held a BEMA Roundtable workshop on 07-08 February 2002 (postponed from 04-05 October 2001 due to issues pertaining to 9/11terrorist attack) at the National Reseach Council (NRC), Washington DC. The invited speakers were Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; Ron Greene, Wilmer, Cutler & Pickering; Barbara Rather, Dow Corning; Nelson Lazear, Bayer; James Harper, PolicyCounsel.com; and George Brode, Integra LifeSciences. The speakers addressed the topic of "pathways to innovation," including examining the current status and gauge the effects of biomaterials shortages, identifying key barriers to biomaterial availability, and discussing forging biomaterials supplier. The workshop provided opportunities to explore with key stakeholders and decision makers future options in assuring biomaterials availability.

NMAB held the fourth BEMA on 22-23 July 2002 at NRC's J. Erik Jonsson Woods Hole Center, Woods Hole, MA. The technical speakers were Nancy Parenteau, Amaranth Bio, Inc.; Joshua Jacobs, Rush University Medical College; Mark Kramer, FDA; Eric Amis, NIST; Doyle Gantt, FDA, Center for Devices and Radiological Health; Anthony Ratcliffe, Advanced Tissue Sciences; Jack Lemons, University of Alabama – Birmingham; Rodney White, UCLA; and Michael Jaffe, Medical Device Concept Laboratory. The meeting goals were to continue planning for a "Science-Based Testing" workshop and to discuss issues of interest including implant retrieval (and associated logistics, database issues, privacy, etc); differentiation of biologics, devices, and combination products; industry perspective of where advanced biomedical materials are headed and their related testing requirements (e.g., nano, MEMS, tissue engineering), and current testing protocols.

The fifth BEMA meeting is scheduled for 19-20 December 2002, to continue planning for the "Science-Based Testing" workshop, now scheduled for 11-12 February 2003.

### Key Research Accomplishments

- A BEMA workshop held, covering topics on "pathways to innovation" in biomaterial research and device innovation.
- Conference call meetings of "science-based testing" planning group
- A BEMA meeting covering topics of science-based testing
- Dates set for next BEMA meeting and for BEMA Workshop

**Reportable Outcomes**

Workshop Presentations by

- Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration – **FDA Regulatory Perspectives**
- Ron Greene, Wilmer, Cutler & Pickering – **Biomaterials Access Assurance Act: Background and Intent of the Act**
- Barbara Rather, Dow Corning; Nelson Lazear, Bayer – **Biomaterials Access Assurance Act: Supplier Perspectives**
- James Harper, PolicyCounsel.com – **Biomaterials Access Assurance Act: Legislative Perspective**
- Julio Palmaz, UTHSCSA – **Interfacial Approach to Vascular Biomaterials**

Meeting Presentations by:

- Alan Goldstein, Alfred University – **Science-based Testing: Discussion of Issues and Envisioning the science-based testing meeting**
- Mark Kramer, FDA – **Science-based testing: Regulation of Combination Products**
- Nancy Parenteau, Amaranth Bio, Inc. – **Science-based testing: Scientific Challenges for Combination Products**
- Joshua Jacobs, Rush University Medical College – **Current ASTM Testing Standards**
- Eric Amis, NIST – **Adopting Combinatorial and High-Throughput Approaches to Measurements at the Bio-Material Interface**
- Doyle Gantt, FDA, Center for Devices and Radiological Health – **Government Agency Perspective**
- Anthony Ratcliffe, Advanced Tissue Sciences – **Industry Perspective**
- Jack Lemons, University of Alabama – **Academic Perspective**
- Rodney White, UCLA – **Lifeline Registry Implant Retrieval Program**
- Michael Jaffe, Medical Device Concept Laboratory Materials – **Medicine, Devices, and Bioterrorism Overview**

**Conclusions**

The BEMA Roundtable held a workshop and a meeting in the past year, providing forums to discuss biomaterials innovation and risk, device innovation, and science-based biomaterials testing. The BEMA will meet in December 2002 to discuss and continue planning for the upcoming 2003 "Science-Based Testing" workshop.